2014-1136
(Serial Nos. 95/000,468 and 90/009,378)

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

DEPUY SYNTHES PRODUCTS, LLC,

Appellant,

v.

SMITH & NEPHEW, INC.,

Appellee.

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT TRIAL AND APPEAL BOARD

BRIEF OF APPELLEE SMITH & NEPHEW, INC.

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July 18, 2014

CERTIFICATE OF INTEREST

Counsel for Smith & Nephew, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Smith & Nephew, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Smith & Nephew, Inc.; Smith & Nephew Holdings, Inc.; Smith & Nephew Consolidated, Inc.; Smith & Nephew Management B.V.; Smith & Nephew USD Limited; TP Limited; Smith & Nephew (Overseas) Limited; Smith & Nephew plc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Hunton & Williams LLP: Bradley T. Lennie, Robert A. King, David A. Kelly, and Jeff B. Vockrodt

Knobbe, Martens, Olson & Bear, LLP: Joseph R. Re and Christy G. Lea.

July 18, 2014
Date

/s/Joseph R. Re
Signature of counsel

Joseph R. Re
Printed name of counsel

TABLE OF CONTENTS

Page No(s).

TABLE OF CONTENTS
(*cont'd*)

Page No(s).

TABLE OF CONTENTS
(*cont'd*)

Page No(s).

TABLE OF AUTHORITIES

Page No(s).

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

OTHER AUTHORITIES

STATEMENT OF RELATED CASES

Smith & Nephew agrees with the Statement of Related Cases submitted by Synthes. In addition, Smith & Nephew submits that this Court's prior precedential decision in *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371 (Fed. Cir. 2013), controls the outcome of the present appeal.

I. COUNTER-STATEMENT OF THE ISSUES

1. In *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371 (Fed. Cir. 2013), this Court held that Synthes' patent claims directed to a bone plate having only threaded holes in the head were unpatentable for obviousness. In that appeal, Synthes chose not to rely on its evidence of secondary considerations. In the present appeal, Synthes has chosen to rely upon that evidence in its attempt to have this Court once again consider the patentability of a bone plate having only threaded holes in the head. Does Synthes' reliance on secondary-consideration evidence allow it to avoid the collateral-estoppel consequences of this Court's prior decision?

2. Even if Synthes could relitigate the patentability of a bone plate having only threaded holes in the head, did the Board correctly hold that such a bone plate was unpatentable for obviousness, where:

a. the prior art presents a strong *prima facie* case of obviousness, as this Court previously determined; and

b. substantial evidence supports the Board's numerous factual findings, including a finding that Synthes failed to show a nexus between its evidence of secondary considerations and the claimed bone plate?

II. COUNTER-STATEMENT OF THE CASE

Appellant Synthes obtained U.S. Patent No. 6,623,486 entitled "Bone Plating System" on September 23, 2003. A7384. The '486 patent is the parent to U.S. Patent No. 7,128,744, whose claims this Court held to be unpatentable for obviousness in a precedential opinion. *See Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371 (Fed. Cir. 2013) ("the Prior Appeal").[1] The '486 patent shares an identical specification with the '744 patent. Moreover, Claim 1 of the '486 patent is directed to virtually the same subject matter as the claims of the '744 patent, and Synthes relies upon the same recited feature for patentability as it did in the Prior Appeal, namely that the head of the bone plate contains only threaded holes.

In 2009, Smith & Nephew requested reexamination of the '744 and '486 patents. *See Smith & Nephew*, 721 F.3d at 1373; A378-438 (*ex parte*); A7278-86 (*inter partes*). It relied on largely the same references in both reexaminations, and the United States Patent & Trademark Office ("Patent Office") granted both requests. *See Smith & Nephew*, 721 F.3d at 1373; A507-15 (*ex parte*); A8083-90 (*inter partes*); A8096-101 (merger). In both reexaminations, the Patent Office rejected all the claims as obvious over multiple prior art combinations and maintained those rejections throughout the proceedings. *See Smith & Nephew*, 721

[1] A copy of the precedential decision is attached hereto in an Addendum.

F.3d at 1373; A8115-8138; A12775-814; A13025-68. Synthes appealed the obviousness rejections to the Board.

In the '744-patent reexamination, the Board reversed the rejections of the claims requiring that the plate head have only threaded holes. *Smith & Nephew*, 721 F.3d at 1373. This Court, however, reversed the Board's decision and held that such claims were unpatentable for obviousness as a matter of law. *Id.*

In the '486-patent reexamination, the Board upheld the rejection of all the claims. A36-66. In addition to finding a number of claims anticipated, the Board relied on this Court's obviousness decision on the '744 patent in finding a *prima facie* case of obviousness. Synthes now appeals the Board's decision as to Claim 1. Just as Synthes did in unsuccessfully arguing the Prior Appeal, it again exclusively relies on the limitation that the head has only threaded holes for patentability.

In an attempt to relitigate the issue, Synthes relies on a footnote in this Court's opinion in the Prior Appeal, in which this Court noted that Synthes did not rely upon "objective indicia of non-obviousness." *Smith & Nephew*, 721 F.3d at 1381 n.7; *see* Br. at 2, 19, 36 n.9. Synthes argues that its products, allegedly embodying the subject matter of Claim 1, were commercially successful and were copied by Smith & Nephew. According to Synthes, this Court should therefore reconsider the patentability of a bone plate having only threaded holes in the head.

But Synthes had a full and fair opportunity to litigate this issue. In fact, it submitted the same alleged secondary-consideration evidence throughout both reexaminations, including a declaration from Rene Haag, Synthes' Global Market Segment Manager for Knees, and a declaration from Clifford Turen, M.D., Synthes' technical expert. *Compare* A11629-41 *with* A14523-35; *also compare* A12890-91 (¶¶58-62) *with* A14570-71 (¶¶71-75). Mr. Haag's declarations are essentially identical and include the same ten exhibits, and Dr. Turen's declaration paragraphs are identical. *Id.* Mr. Haag and Dr. Turen provided almost all of the evidence that Synthes relies on for its renewed commercial-success arguments. Br. at 25-26. Synthes provided no evidence of Smith & Nephew's product or alleged copying in either reeexamination. That Synthes elected not to rely upon evidence of commercial success or any other secondary consideration in defending the Board's decision during the Prior Appeal should not allow Synthes to relitigate the same patentability issue in the present appeal.

III. COUNTER-STATEMENT OF THE FACTS

A. Hybrid Bone Plate Technology

The ’486 and ’744 patents relate to orthopedic bone plates. This appeal, like the Prior Appeal, turns on the structure of the bone plate holes, specifically that the head of the plate must contain only holes having a thread. The shaft may contain both threaded and non-threaded holes, but must contain a plurality of non-threaded holes. Plates that contain both threaded and non-threaded holes are sometimes referred to as “hybrid” bone plate technology.

The threaded holes are designed to mate with the thread on the head of a locking screw, or, if a surgeon elects, they can accept non-locking screws, which have non-threaded, smooth heads. A7395 (2:12-14); A7397 (6:37-49). Using a locking screw in a threaded hole provides the advantage of locking the screw to the plate to prevent toggling of the plate as the patient moves around post-operatively. A7395 (1:46-59). Using a non-locking screw, which does not lock to the plate, allows the plate to be compressed to the bone as the screw is drilled into the bone. *Id.* (1:60-65). Using a mix of locking and non-locking screws allows for both compression and a fixed, locked construct.

B. The Previously Invalidating Prior Art

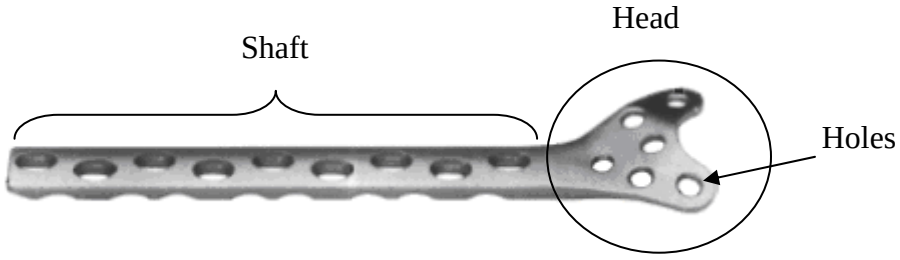
This appeal involves the same prior art as that previously reviewed and relied upon by this Court in the Prior Appeal. *Smith & Nephew*, 721 F.3d at 1374-

75. Here, like in the Prior Appeal, it is undisputed that the prior art discloses every limitation of the challenged claim. A12808.

Synthes' Statement of the Facts relies on its experts' characterization of the primary references, while ignoring that Smith & Nephew presented contrary evidence. Br. at 7-9 (repeatedly citing to Parsons and Turen declarations). It also omits any discussion of the prior art references showing that one of ordinary skill knew that non-locking screws could be used in holes having a thread as this Court held in the Prior Appeal. *Smith & Nephew*, 721 F.3d at 1379. Thus, Smith & Nephew provides the following discussion of the prior art.

1. <u>The Primary References: Condylar Buttress Plates</u>

For more than 75 years, surgeons have used condylar buttress plates to improve the stability of a bone fracture in the distal femur (the portion of the thigh bone adjacent to, and extending above, the knee joint). A6310 (Colin Catalog); A6422 (English translation). In the 1990s, Synthes marketed a condylar buttress plate having a shaft and a head with smooth, non-threaded holes. A12858-59.



In 1996, years before Synthes filed the '486 provisional patent application, Dr. Brett Bolhofner, one of the named inventors on the '486 and '744 patents, co-authored an article explaining the advantages of modifying this condylar buttress plate to allow surgeons the option of using either locking or non-locking screws:

> It appeared obvious that some minor modifications to the condylar buttress plate allowing a selected locking of the screws to the plate in a physiological angle would avoid some of the previously noted problems with this particular device and may further expand its use.

A6572;[2] *see also Smith & Nephew*, 721 F.3d at 1374.

In 1997, Dr. Kenneth Koval and others published an article in which they concluded that a "condylar buttress plate using locked screws is a valid concept to maximize fixation stability" in fractures. A92.[3] Dr. Koval compared the fixation stability of a standard condylar buttress plate with a modified condylar buttress plate in which the screws in the head locked to the plate. A86. For the modified plate, he welded threaded nuts on top of the holes in the head in the same pattern that he had used for inserting four screws in the standard plate and then inserted screws that locked to the plate in the four threaded holes. A87. As with the

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[2] Bolhofner et al., *The Results of Open Reduction and Internal Fixation of Distal Femur Fractures Using a Biologic (Indirect) Reduction Technique*, Journal of Orthopaedic Trauma, Vol. 10, No. 6, 1996. A6568-73.

[3] Koval et al., *Distal Femoral Fixation*, Journal of Orthopaedic Trauma, Vol. 11, No. 7, Oct. 1997. A86-95.

standard plate, Dr. Koval did not place any screws in the other two holes. A12968. The resulting plate (with screws locked to the plate) is shown below.

A88.

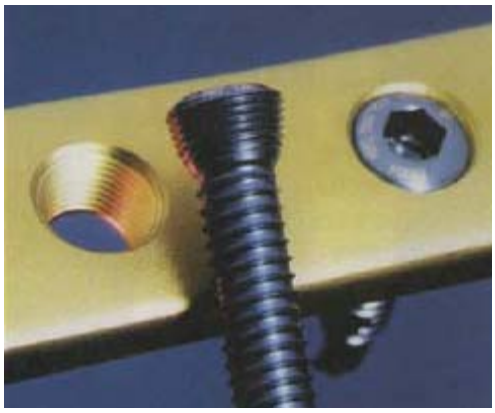
In 1998, Synthes submitted an application with the U.S. Food and Drug Administration (the K982222 Summary) seeking approval for a hybrid bone plating system. A6681.[4] That system, like the modified Koval plate, had four threaded holes and two non-threaded holes in the head of the plate. *Id.* The K982222 Summary explained that "[t]he primary feature of the plate and screw system is that the 7.3 mm locking screws engage with the head of the plate to form a locked, fixed angle construct." *Id.* Neither the Koval plate, nor the K982222 plate, was ever commercialized.

2. <u>The Secondary Reference: Only Threaded Screw Holes</u>

In 1997, Dr. N.P. Haas and others published an article that described a Synthes' locking bone plating system known as the Less Invasive Stabilization

[4] Synthes, *Synthes Condylar Buttress Plates*, FDA Website, July 1998 ("K982222").

System (LISS), which is also used to treat fractures in the distal femur. A7230; A7238-46 (English translation).[5] The LISS plating system has a plate with a head and a shaft. A7235. The LISS plate employs only threaded screw holes throughout the entire plate, including the head. A7242; A11325. Haas shows the threaded hole and mating screw head in the following figure:



A7234; A13842. The Haas threaded holes have a conical shape, which was important in the Prior Appeal, because Claim 1 of the '744 patent required conically shaped holes. In this appeal, however, Claim 1 of the '486 patent does not specify the shape of the holes.

3. Knowledge Of Using Non-Locking Screws In Threaded Holes

a. DRP Plates

Before 1997, Synthes marketed another bone plating system known as the Distal Radius Plate (DRP), which was used to treat fractures in the distal radius or

[5] Haas et al., *LISS-Less Invasive Stabilization System*, OPJOURNAL, 3:13, pp. 340-344, Dec. 1997 ("Haas"). A7230-37.

wrist bone. A96-106. The DRP system has only threaded holes in the "distal arm" of the plate, which a surgeon would place on the head of the distal radius. A97. The threaded holes in the DRP plate accept either "threaded buttress pins that lock into the threaded plate holes" or non-locking screws, referred to as "self-tapping cortex screws." A97. A surgeon has the option of using a combination of these pins and screws. A102.

b. LRP Plates

Synthes also marketed another device known as the Locking Reconstruction Plate (LRP) in 1997. A6618-25 (LRP Guide); A12406-11 (LRP Article translation); A12397-403 (LRP Article original). Similar to the DRP system, LRP is an internal fixation system for the mandible or lower jaw bone that uses only threaded holes throughout the plate. A6620. Each of these threaded holes allows for "the option of [a] locked or standard screw." A6619. As such, the LRP system allows for both locking and compression. A12407.

In 1995, Synthes filed a PCT application for a bone plate similar to the LRP plate. That application issued as U.S. Patent No. 5,709,686. A11992-98. The stated "object" of the '686 patent is to create a bone plate having holes that are "designed selectively to make possible two different kinds of screw anchorings." A11997 (1:20-23). More specifically, the '686 patent discloses threaded holes that accommodate either locking screws or non-locking screws. *Id.* (2:65-67). The

patent explains that by using a non-locking screw, the plate achieves a "compressive effect." *Id.* (1:23-28).

In the '486 patent, the Background of the Invention expressly discusses the '686 patent. It explains that the '686 patent showed a prior art bone plate with threaded holes where the "threaded holes allow either non-locking or locking screws to be used." A7395 (2:12-14).

C. The '486 Patent

1. The Disclosure

The '486 patent characterizes the invention as hybrid plating. A7384. The patent discloses: "By combining locking screws and non-locking screws on the same bone plate, the present invention provides a novel mixed fixation." A7397 (5:31-33); A11326-28. Apparently, at the time this disclosure was written, the drafter of the patent was not aware of the Koval or K982222 hybrid plates, because both prior art references teach "combining locking screws and non-locking screws on the same bone plate." A87; A6681.

Figure 3 from the '486 patent shows a portion of the bone plate. A7387. In explaining Figure 3, the patent discloses that the bone plate "can be made in different shapes and sizes for use in a wide variety of clinical applications." A7396 (4:41-44). The patent discloses the following features of the bone plate:

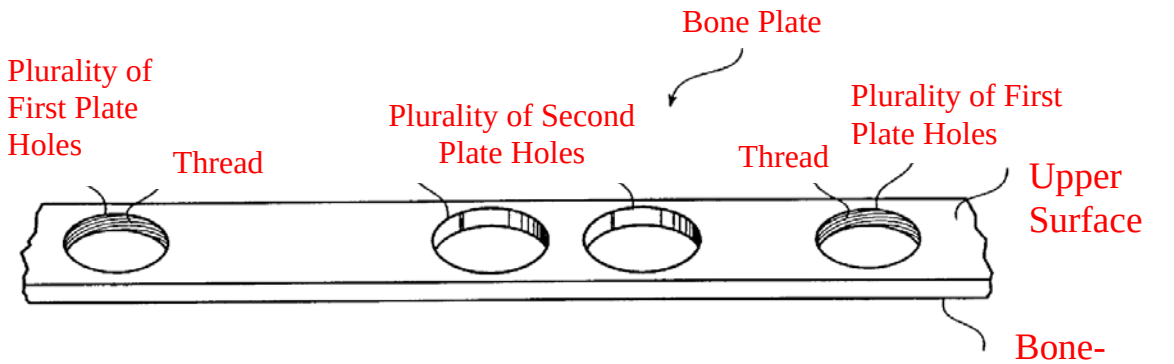


Fig. 3

A7387; A7396 (4:41-67). The patent explains that each first plate hole has a thread that mates with the thread on the head of a locking screw. A7396 (4:48-51). It further explains that second plate holes "are not threaded" and receive non-locking screws with non-threaded heads. A7396 (4:52-53).

Figure 7 from the '486 patent shows one embodiment of the plate, specifically designed for use in the distal femur:

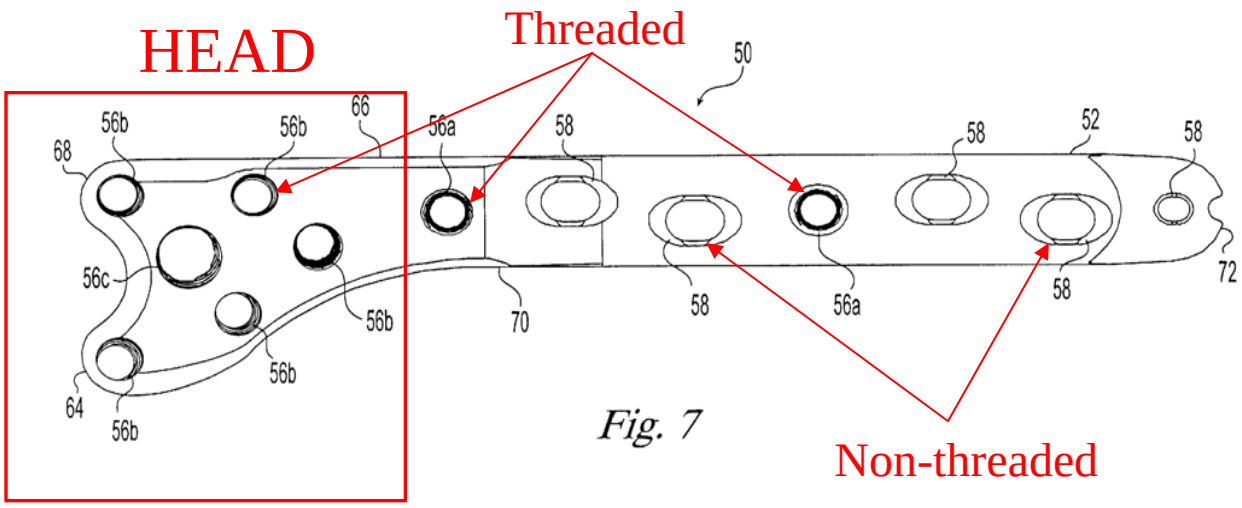
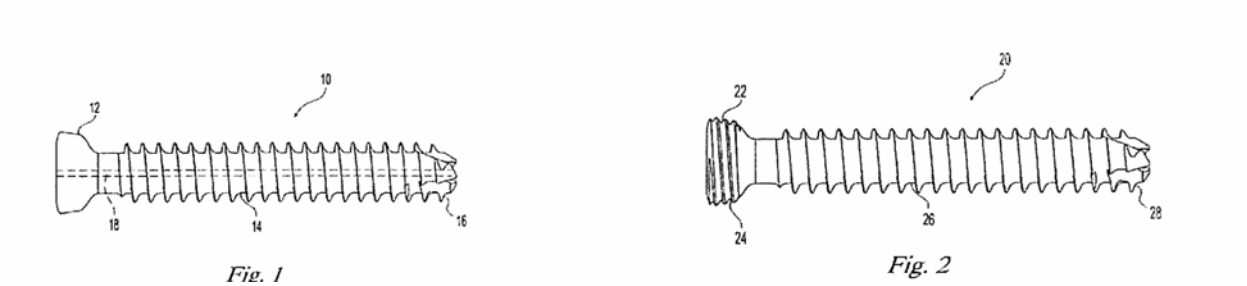


Fig. 7

A7389. In explaining Figures 7-19, the patent discloses that the bone plate has threaded holes 56 for receiving locking screws 20 and non-threaded holes 58 for receiving non-locking screws 10. A7397 (5:66-6:4). The patent attributes no significance to the screws so long as they are of an "appropriate size and geometry" for the holes; thus "any surgical screw that has a threaded head" can be used as the locking screws, and "any surgical screw that has a non-threaded head" can be used as the non-locking screws. A7396 (4:16-19). The patent discloses an example of a non-locking screw 10 and a locking screw 20 in Figures 1 and 2, respectively.



A7386.

Unlike the shaft, which may contain both threaded and non-threaded holes, the head of the plate contains only threaded holes 56. A7397 (6:37-38). Those threaded holes accommodate locking screws, but, as the patent explains, "if a surgeon elects, non-locking screws can be used in any of threaded plate holes 56." *Id.* (6:48-49). The patent discloses other embodiments that do not have only threaded holes in the head. *See* A7397-98 (6:58-7:44).

2. The Appealed Claim 1

Synthes has limited its appeal to Claim 1. Br. at 18 n.6. The parties agree that "Claim 1 of the '486 patent recites, *inter alia*, a bone plate having a head portion with exclusively threaded holes." Br. at 12. It also requires that the shaft have non-threaded holes. Claim 1, with the most relevant limitations emphasized, is shown below:

> 1. A bone plate system for fixation of bone comprising:
>
> a bone plate having:
>
> an upper surface;
>
> a bone-contacting surface;
>
> ***at least one first hole*** passing through the upper and bone-contacting surfaces and ***having a thread***; and
>
> at least one second hole passing through the upper and bone-contacting surfaces;
>
> a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the thread of the first hole; and
>
> a second screw having a shaft with a thread for engaging bone and a head, wherein the first and second screws remain seated in their respective holes for substantially as long as the bone plate is implanted,
>
> wherein the bone plate includes a plurality of first and second holes, and a corresponding plurality of first and second screws are provided, and
>
> wherein the bone plate includes a head portion configured and dimensioned to conform to a metaphysis of a bone and a shaft portion configured and

dimensioned to conform to a diaphysis of a bone and ***the head portion has only first plate holes***.

In all respects relevant to this appeal, Claim 1 of the ’486 patent is identical to Claim 1 of the Prior Appeal. Both claim a bone plate having both threaded and non-threaded screw holes with the head of the plate having only threaded screw holes. Whereas Claim 1 in the ’744 patent explicitly recites that the holes are threaded and non-threaded, Claim 1 of the ’486 patent refers to those same holes as first and second plate holes, respectively. *See, e.g.*, A55 (Board interpreting “first and second plate holes” in ’486 patent to mean “threaded and unthreaded holes,” respectively); Br. at 12.

D. Synthes’ Prior Art Condylar Buttress Plates

Synthes is the market leader for plating devices. A11630. Synthes developed most of the prior art to the ’486 patent, but commercialized only some of it.

1. Synthes Sold Condylar Buttress Plates Containing Non-Threaded Holes

Since at least 1994, Synthes has sold standard condylar buttress plates (“CBP”) in which every hole in the plate was smooth (*i.e.*, did not contain a thread). A11638; A12858-59. Synthes sold two different types of CBP plates: Dynamic Compression Plates (DCP) and Low Contact, Dynamic Compression Plates (LC-DCP). *Id.* Synthes sold its non-threaded DCP and LC-DCP plates with

non-locking screws. *Id.* When a surgeon inserted the screws into the smooth holes and drilled them into the bone, the screws compressed the plate to the bone. *Id.*

2. Synthes Publicly Disclosed Hybrid Plates That It Never Commercialized

As previously discussed, in 1997 and 1998, Dr. Koval published an article and Synthes filed the K982222 510-K summary disclosing hybrid plates having both threaded and non-threaded holes for use with locking and non-locking screws. Synthes, however, never commercialized either the Koval or the K982222 hybrid plating devices.

E. Synthes Later Commercialized Its Locking Compression Plates

In March 2001, Synthes introduced into the United States market its Locking Compression Plate ("LCP") products. A11637. Synthes was the first company to launch and sell products in the hybrid plate market. A11638.

Synthes alleges that three of its LCP plates are commercial embodiments of Claim 1 of the '486 patent. Br. at 25 (citing A11636). Specifically, Synthes alleges that the following three plates are covered by Claim 1: (1) 4.5mm LCP Condylar Buttress Plate; (2) 3.5 mm LCP Proximal Tibia Plate; and (3) 4.5mm LCP Proximal Tibia Plate ("4.5mm Tibia"). *Id.* Despite material differences among the plates, Synthes has treated all three plates as identical, grouping them under the designation "LCP plate(s)" or "LCP product(s)." *See, e.g.*, Br. at 14-15; 23 n.7; 25-26, 34.

Synthes' LCP plates are sold and used as part of a broad system that includes much more than plates and screws. A12420. Each plate system contains 22-32 different components and instruments, depending upon the plate. A12420-22. Many of those components contain unique features that are different from other companies' systems. A12423. Moreover, the LCP plates themselves contain features that are not patented features of the '486 patent. A12424-25; A11540-73; A11576-97; A11600-28.

Because Synthes is the market leader in the U.S. plate and screw market, it enjoys significant advantages when selling its bone plating systems. A12429. Smith & Nephew submitted evidence that surgeons and hospitals purchase bone plate and screw systems based on brand loyalty, relationships with sales representatives, and group purchasing organization (GPO) memberships. A12425-29.

F. <u>The Examiner's Rejections</u>

On reexamination, the Examiner rejected Claim 1 of the '486 patent as obvious over the following prior art:

- Primary Reference K982222, both alone (Ground 28) and in combination with Secondary Reference Haas (Ground 30); and
- Primary Reference Koval in combination with Secondary Reference Haas (Ground 89).

A13034-41. Smith & Nephew relied on two declarations from its technical expert, Lawrence Marsh, M.D., explaining the reasons why a person of ordinary skill would be motivated to modify or combine the prior art references. A12073-128; A12965-75.

In the Action Closing Prosecution, the Examiner found that combining any of the condylar buttress plates disclosed in the two primary references with the threaded holes in Haas taught all of the claim limitations. A12809-10. The Examiner observed that Synthes did not dispute that "the respective functions of all of the claimed limitations are the same as the respective functions of those features in the applied art and the prior art of record." A12810. The Examiner further observed that Synthes had not even argued that by threading all the holes in the head of an otherwise known bone plate, the resulting plate functioned in a surprising or unexpected way. *Id.*

The Examiner incorporated all of the evidence and reasons Smith & Nephew identified as to why the secondary considerations of commercial success and copying could not overcome the *prima facie* case of obviousness. A12810-11 (incorporating by reference A12547-59). First, Synthes failed to show that the commercial LCP plates were commensurate in scope with the claims. A12550. Second, Synthes failed to show that any alleged commercial success was due to the merits of the claimed invention beyond what was disclosed in the prior art.

A12549-50. Synthes ignored prior art (Koval and K982222) that was never commercialized, instead comparing its success to the standard condylar buttress plates having no threaded holes. *Id.* Third, Synthes' alleged success was due to unclaimed features as well as other economic and commercial factors. A12550-59. Fourth, Synthes submitted no evidence whatsoever to support its claim that its products were copied. A12559. Smith & Nephew supported its rebuttal to Synthes' arguments on secondary considerations with a declaration from Michael Donoghue, Vice President Global Trauma Marketing at Smith & Nephew. A12419-30.

In the Right of Appeal Notice, the Examiner again agreed with Smith & Nephew's position that Synthes had failed to establish a nexus between commercial success and the claimed invention and again incorporated Smith & Nephew's arguments. A13063 (incorporating by reference A12925-29).

G. The Board's Affirmance

After the hearing before the Board, but before issuance of the Board's Decision, this Court issued its opinion in the Prior Appeal. Relying in part on this Court's prior opinion, the Board affirmed the Examiner's finding that the appealed claims, including Claim 1, would have been obvious. A39.

1. Prior Federal Circuit Appeal

This Court held that Smith & Nephew presented "compelling evidence that it would have been obvious to modify any one of the three primary references [including Koval and K982222] to have only threaded holes in the head portion." *Smith & Nephew*, 721 F.3d at 1380. This Court held that one of ordinary skill would have been motivated to use more threaded holes and locking screws in the head of the plate to maximize the stability of the head of the plate. *Id.* at 1377. This Court also held that one of ordinary skill would have been motivated to use only threaded screw holes in the head to give the surgeon the option during surgery to use either locking screws or non-locking screws in the threaded holes, depending on whether the surgeon preferred stabilization or compression. *Id.* at 1375.

This Court rejected Synthes' argument that achieving compression with non-locking screws in threaded holes was unknown in the prior art and would have made the plate inoperable. *Id.* at 1381. This Court also rejected Synthes' claim that it invented a "specialized screw" in light of the disclosure in the specification that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry for select plate holes of the bone plate can be used." *Id.* (quoting '744 patent, 4:18-22); *see* A7396 (4:17-19). Therefore, this Court held that the disputed claims would have been obvious.

2. Board's Decision In This Appeal

The Board correctly observed that Synthes' arguments in support of patentability were substantively the same as those presented and rejected by this Court in the Prior Appeal. A51. The Board determined that this case, however, differed because, Synthes did not rely upon its evidence of commercial success in the Prior Appeal. A51-52. Therefore, the Board considered the obviousness of the claims at issue in view of Synthes' proffered evidence of commercial success, holding that Synthes failed to establish sufficient nexus between the claimed invention and any commercial success. A52; A62-65.

The Board observed that Synthes' LCP products, while commercially successful, were not covered by Claim 1. A64. Moreover, the Board found that the LCP plates contain unclaimed components that Synthes advertised as being desirable features of its products. A63-64. The Board also found that other market and commercial factors may have had significant bearing on the commercial success of the LCP products. A64. The Board concluded that Synthes failed to adequately address the evidence presented by Smith & Nephew and failed to offer rebuttal evidence regarding the impact of the unclaimed features and other market factors on commercial success. *Id.* Finally, the Board found that Synthes had not submitted any evidence of copying. A65.

Accordingly, the Board held that "it would have been obvious to one of ordinary skill in the art to modify a condylar buttress plate having a head portion that includes unthreaded bone anchor holes as described in K982222 or Koval so as to only provide holes having a thread in the head portion." A65.

IV. SUMMARY OF THE ARGUMENT

Synthes is not entitled to have this Court rule again on the patentability of a bone plate having only threaded holes in the head. Synthes incorrectly argues that this Court must consider that issue "anew" because Synthes did not present "objective indicia of non-obviousness" in the Prior Appeal. But Synthes ignores that collateral estoppel precludes it from relitigating an issue where it had a full and fair opportunity to do so in a prior action. Having presented the exact same evidence in both reexaminations, Synthes cannot argue that it lacked a full and fair opportunity to present its secondary considerations evidence in the Prior Appeal.

Even if Synthes could relitigate the obviousness issue, substantial evidence supports the Board's finding of no nexus. Synthes has not even shown that its LCP products are covered by, or are coextensive with, Claim 1. Moreover, its own employee and expert testified that the success of its LCP plates was due to their hybrid nature, a feature plainly shown in the Koval and K982222 prior art. Finally, Smith & Nephew submitted further evidence showing that the success was due to unclaimed features and market factors.

This Court previously held that the closest prior art presents a strong *prima facie* case of obviousness. Synthes' weak evidence of secondary considerations cannot overcome that strong *prima facie* case. Accordingly, the Board's decision that Claim 1 is unpatentable for obviousness should be affirmed.

V. ARGUMENT

A. Standard of Review

The Board did not rely upon the doctrine of collateral estoppel, presumably because this Court's decision in the Prior Appeal issued after the parties' submitted their arguments to the Board. Nevertheless, this Court is free to apply the doctrine in the first instance. *Arizona v. California*, 530 U.S. 392, 412 (2000); *Transclean Corp. v. Jiffy Lube Int'l, Inc.*, 474 F.3d 1298, 1308 (Fed. Cir. 2007); *Alyeska Pipeline Serv. Co. v. United States*, 688 F.2d 765, 771 (Ct. Cl. 1982).

This Court reviews the Board's ultimate determination of obviousness *de novo* and the Board's underlying factual findings for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). In Patent Office reexaminations, "the standard of proof—a preponderance of the evidence—is substantially lower than in a civil case and there is no presumption of validity in reexamination proceedings." *Q. I. Press Controls, B.V. v. Lee*, No. 2012-1630, 2014 U.S. App. LEXIS 10624, *13 (Fed. Cir. June 9, 2014).

Like the other inquiries underlying an obviousness analysis, whether a patentee has established the requisite nexus between the claimed invention and any secondary considerations is a question of fact that this Court reviews for substantial evidence. *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 736 (Fed. Cir. 2013). A factual finding is supported by substantial evidence if a

reasonable mind might accept the evidence to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938).

B. Collateral Estoppel Precludes Synthes From Re-Arguing The Non-Obviousness Of A Bone Plate Having Only Threaded Holes In The Head

Synthes argues that this Court should consider "anew" the patentability of a bone plate having only threaded holes in the head, even though this Court previously considered this same issue in the Prior Appeal. Br. at 35, 40. However, the doctrine of collateral estoppel protects a party, like Smith & Nephew, from having to relitigate an issue that was fully and fairly litigated in a prior action and adversely resolved against a party-opponent, like Synthes. *See Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). So long as "the identical issue was fully litigated in a prior suit between the same parties or their privies, and that resolution of the issue was essential to the judgment in the prior suit," collateral estoppel applies. *Amgen, Inc. v. Genetics Inst., Inc.*, 98 F.3d 1328, 1331 (Fed. Cir. 1996). This appeal satisfies each of these requirements.

First, this appeal involves the same parties as the Prior Appeal. Second, Synthes presents the identical issue here as it presented in the prior appeal, namely the obviousness of a bone plate having only threaded holes in the head. *See* Br. at 25 (relying on a single limitation of Claim 1 for patentability: "the presence of threaded holes, and ***only*** threaded holes, in the head of the plate") (emphasis in

original); *see also id.* at 15, 32. Third, Synthes had a full and fair opportunity to litigate the obviousness of a bone plate having only threaded holes in the head in the prior reexamination. Indeed, Synthes presented the same evidence throughout both reexaminations, including virtually identical declarations and all the same exhibits. *See supra* pages 3-5. Fourth, this Court's holding that a bone plate having only threaded holes in the head would have been obvious was essential to its reversal of the Board's decision in the Prior Appeal.

Synthes, however, argues two reasons why it should be entitled to relitigate the patentability of such a bone plate: (1) "the claims presented here are different from the claims previously considered by this Court" and (2) "Synthes presented undisputed and powerful evidence of commercial success." Br. at 19-20. Both of these arguments fail to overcome the collateral-estoppel effect of the final decision in the Prior Appeal.

Regarding any differences in the claims, this Court has held that claims need only be "substantially similar" for collateral estoppel to apply to the issue of obviousness. *Ohio Willow*, 735 F.3d at 1342. In *Ohio Willow*, this Court considered whether collateral estoppel applied to preclude patent owner, Ohio Willow, from litigating the non-obviousness of certain claims when substantially similar claims of a related patent had been declared invalid for obviousness. Ohio Willow argued that "the mere existence of different language" in the adjudicated

and unadjudicated claims is sufficient to overcome collateral estoppel. *Id.* This Court rejected that argument, holding that "it is the identity of the issues that were litigated that determines whether collateral estoppel should apply." *Id.* Specifically, "[i]f the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.* This Court put the burden on the party opposing collateral estoppel to explain how any "alleged differences in claim scope alter the invalidity determination." *Id.* at 1343. When Ohio Willow failed to meet that burden, this Court affirmed the application of collateral estoppel to the substantially similar claims.[6]

Here, Synthes has pointed to one difference between Claim 1 of the '486 patent and the adjudicated claims of the '744 patent, namely that Claim 1 recites screws and the '744 patent claims did not. Br. at 19. But at no point in its brief does Synthes attribute any patentable significance to this distinction. Indeed, the prior art discloses the screws, A6311-12; A6423-24, and the '486 patent admits that "any surgical screw" may be used in any of the holes, A7396 (4:17-34). Thus,

[6] In so doing, this Court adopted the binding precedent of one of its predecessor courts, the Court of Claims. *See Ohio Willow*, 735 F.3d at 1342 (citing *Bourns, Inc. v. U.S.*, 537 F.2d 486, 491 (Ct. Cl. 1976); *Westwood Chem., Inc. v. U.S.*, 525 F.2d 1367, 1372 (Ct. Cl. 1975)).

the entire focus of Synthes' non-obviousness argument rests on the only-threaded-holes-in-the-head feature.

Moreover, the claims in *Ohio Willow* differed in scope, with the adjudicated claims broadly requiring a "polymeric" gel and the unadjudicated claims more narrowly requiring a "block copolymer" gel. *Id.* at 1343. This Court held that such a difference did not preclude collateral estoppel, because Ohio Willow "failed to explain how the 'block copolymer' limitation changes the invalidity analysis." *Id.* Here, Synthes did not argue that reciting screws in the claim changed the invalidity analysis in any way.

Regarding Synthes' evidence of commercial success, Synthes cannot sidestep collateral estoppel by now choosing to rely upon its commercial success evidence. "The party opposing a plea of estoppel must establish that it did not have a full and fair opportunity to litigate; it must demonstrate that without fault of his own the patentee was deprived of crucial evidence or witnesses in the first litigation." *Dana Corp. v. NOK, Inc.*, 882 F.2d 505, 508 (Fed. Cir. 1989). Synthes cannot meet this standard, because it actually did present the same commercial success evidence throughout the '744 patent reexamination. *See supra* page 5. That Synthes chose not to rely upon that evidence in the Prior Appeal in no way suggests that it was deprived of the opportunity to do so. Synthes must live with the choices it made in the last appeal. *See Simmons v. Small Bus. Admin.*, 475 F.3d

1372, 1374 (Fed. Cir. 2007) (applying collateral estoppel and barring new arguments because it is reasonable to require a party to bring forward all evidence in support of its argument in the initial proceeding). Smith & Nephew should not have to relitigate, nor should this Court have to re-decide, the obviousness of a bone plate having only threaded holes in the head, merely because Synthes chose to omit certain arguments from the Prior Appeal. Accordingly, the Board's rejection of Claim 1 of the '486 patent as unpatentable for obviousness should be affirmed under the doctrine of collateral estoppel.

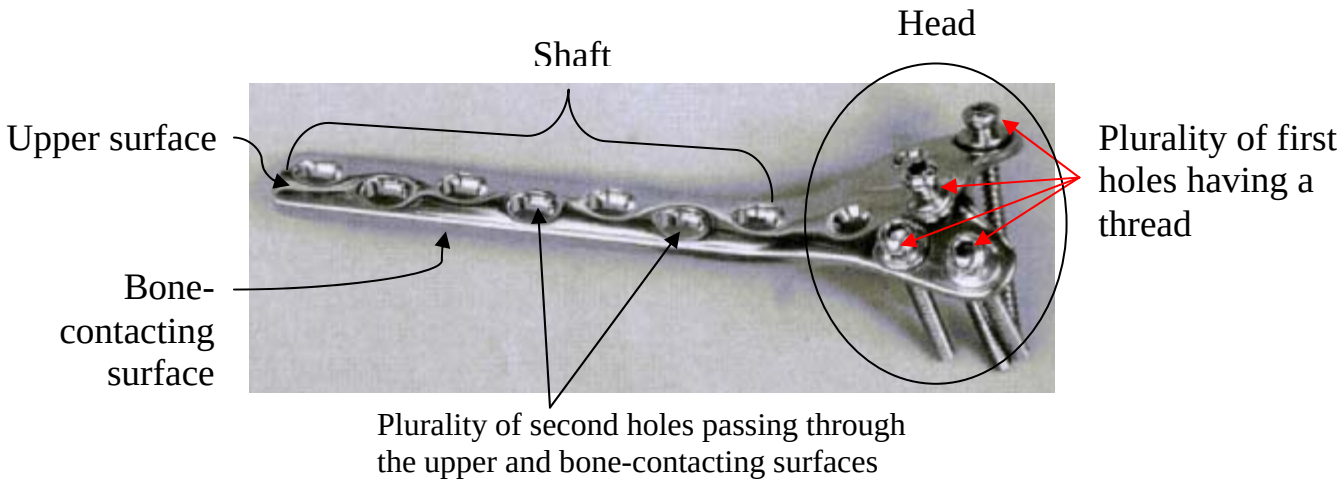
C. The Board Correctly Upheld The Examiner's Rejection Of Claim 1 As Unpatentable For Obviousness

Even if Synthes could relitigate the obviousness issue, this Court should nonetheless affirm because the Board correctly upheld the Examiner's obviousness rejection of Claim 1. A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. 35 U.S.C. § 103(a). An obviousness determination is based on underlying factual inquiries including (1) the scope and content of the prior art; (2) the differences between the prior art and the claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). As this Court previously held with respect to the similar claims of the '744 patent, the invention of Claim 1 would have been

obvious as a matter of law. Moreover, the Board's findings underlying its decision are supported by substantial evidence.

1. Substantial Evidence Supports The Board's Findings Regarding The Primary Obviousness Factors

The prior art references undisputedly disclose every limitation of Claim 1. A12808. The photograph below from the Koval article shows a bone plate having almost all of the recited features of Claim 1:



A88. The Koval article also discloses two different types of screws. A87. K982222 discloses a bone plate having the same features, as well as locking and non-locking screws. A6681. Haas discloses a bone plate having only threaded screw holes in the head. A7242; A11325. Thus, the prior art references disclose every limitation of Claim 1. Moreover, the Board correctly found a motivation to modify Koval or K982222 to have only threaded holes in the head for all of the reasons set forth in this Court's opinion in the Prior Appeal. A51. On this appeal, Synthes has made no arguments not already rejected by this Court in the Prior

Appeal, except for its withheld commercial success and copying arguments. Those arguments are addressed below.

2. Substantial Evidence Supports The Board's Finding That Synthes Failed To Establish A Nexus Between The Claimed Invention And Any Commercial Success

The Board found that Synthes' evidence of commercial success is "inadequate to establish nexus between the claimed invention and the commercial success." A52. "Evidence of commercial success . . . is only significant if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). Substantial evidence supports the Board's finding of a lack of nexus between Synthes' evidence and Claim 1 of the '486 patent.

a. Synthes Was Not Entitled To A Nexus Presumption

i. The Board Correctly Found That Claim 1 Does Not Cover Synthes' LCP Products

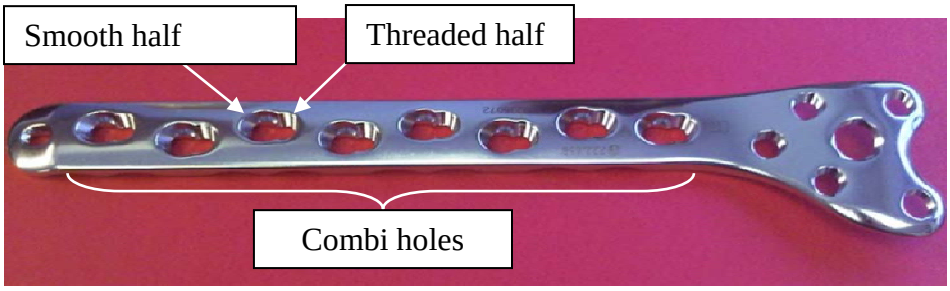
Synthes argues that the Board erred by not affording Synthes a presumption of nexus. Br. at 22-23. But Synthes was not entitled to a presumption, because it failed to prove that its products are covered by Claim 1. For a presumption that any commercial success is due to the patented invention to apply, the patentee "must show that the successful product is the invention disclosed and claimed in the patent." *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1339 (Fed. Cir. 2010). The Board correctly found that Synthes failed to show that

its LCP products were covered by Claim 1. A64. Synthes completely ignored this finding in its opening brief, assigning no error to it.

Synthes wrongly argues that "[t]here is no dispute that the LCP plates embody the invention of the '486 patent." *See, e.g.*, Br. at 23 n.7 (citing A11636). First, Synthes has the burden to show that the LCP plates embody Claim 1, not the '486 patent in general.[7] Second, Synthes merely cites to the declaration of Mr. Haag — Synthes' own employee. Smith & Nephew has never agreed that the LCP plates embody every limitation of Claim 1.

Substantial evidence supports the Board's finding for two different reasons. First, the LCP plates do not contain second (*i.e.*, non-threaded) screw holes in the shaft. Rather, the shaft contains a third type of screw hole, called a Combi hole. A11543; A11579; A11603. A Combi hole is a combination between a threaded hole and a smooth hole, whereby half of the circumference of the hole is threaded and half is smooth, as shown below:

[7] Before the Board, Synthes challenged the Examiner's obviousness determination with respect to additional claims that may have covered one or more of the LCP Plates. A38; A52-A55 (noting that Claims 16 and 17 do not recite that the head has only threaded holes); A7398 (*see also* method claim 10, which does not require the plate have particular holes). Synthes, however, has limited its appeal to Claim 1. Br. at 18 n.6.



A11635. Synthes patented its Combi hole in U.S. Patent No. 6,669,701, which includes the following figure showing the Combi holes having a thread:

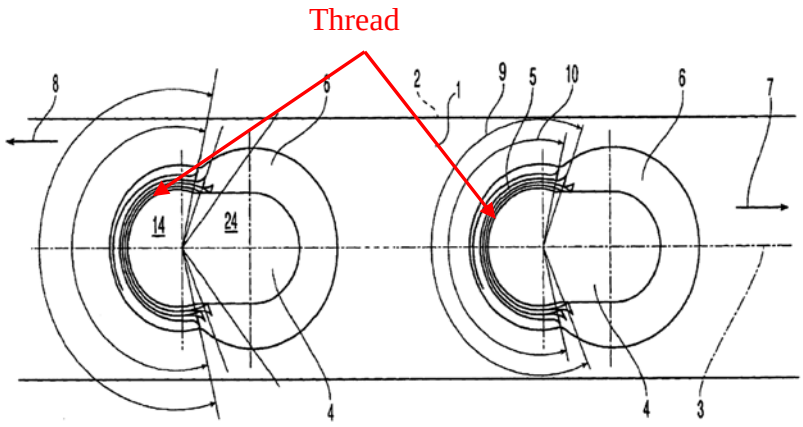


Fig. 1

A12551-52; A14572-81 (cited in A11103). Moreover, Synthes' expert testified that the (Combi) holes in the shaft of the LCP plates are "threaded." A12890. [8] Thus, Synthes cannot meet its burden to show that Claim 1 covers the LCP plates.

Moreover, the 4.5mm tibia LCP plate has both threaded and non-threaded screw holes in the plate head, whereas Claim 1 requires the plate head have ***only***

[8] Synthes acknowledges its expert's admission, but mistakenly asserts that the bone plate of Claim 1 has a shaft having at least one threaded hole. Br. at 25-26. In fact, the shaft must have a plurality of non-threaded holes. A7398 (7:66-67, 8:8-10; 8:14-15).

threaded screw holes. Apparently, Synthes presumes that the head is limited to the area containing the three holes closest to the condyle. But that presumption is inconsistent with the patent, which makes clear that the head is not so limited. Figure 21 from the '486 patent shows "the head portion 90 contains threaded holes 86 ***and*** non-threaded holes 88." A7398 (7:32-34). The head even includes threaded plate hole 86c. *Id.* (7:33-44).

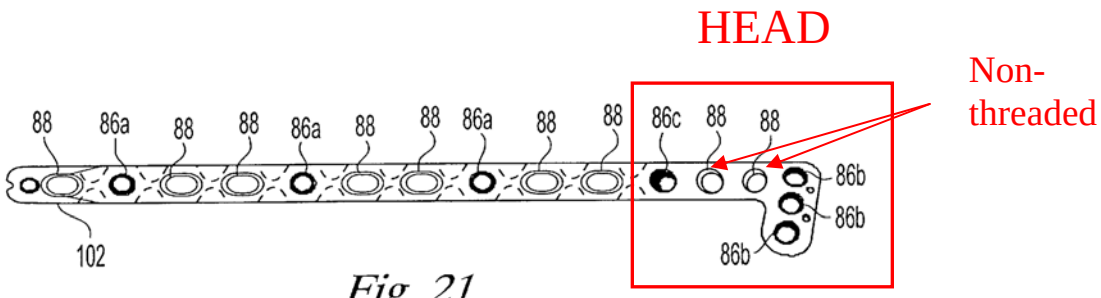
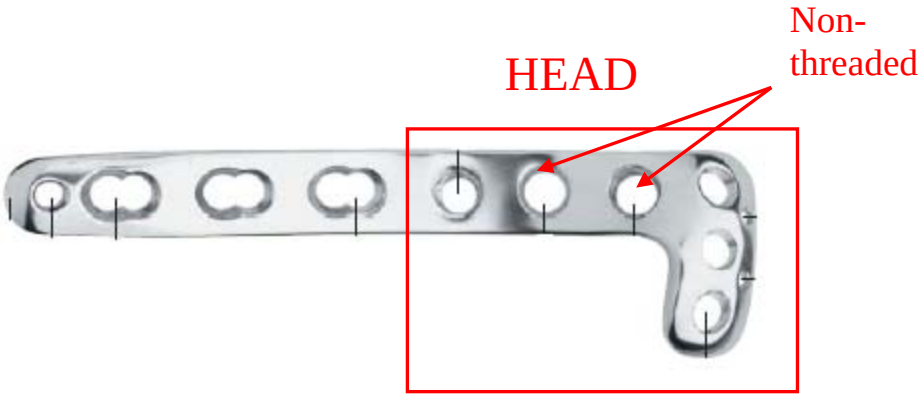


Fig. 21

A7393. Like Figure 21, Synthes' 4.5mm tibia LCP plate, shown below, contains non-threaded holes in the position of holes 88. It also has a threaded hole that corresponds to hole 86c in Figure 21. Thus, Synthes' presumption that the head is limited to the three threaded holes corresponding to 86b is incorrect.



A11603.

Citing the Haag declaration, Synthes argues that its LCP products "embody each and every limitation of Claim 1," including "the presence of threaded holes, and ***only*** threaded holes, in the head of the plate." Br. at 25 (emphasis in original). However, the Haag declaration plainly shows two non-threaded screw holes in the head of the 4.5 mm tibia plate. A11633. Moreover, it shows only Combi holes (which have threads) in the shaft in all three plates. A11633-35. Accordingly, Synthes was not entitled to a presumption of nexus.[9]

ii. <u>The Board Correctly Found That Synthes' LCP Products Are Not Coextensive With Claim 1</u>

Synthes was also not entitled to a presumption of nexus because it failed to prove that its products are coextensive with Claim 1. To rely on a presumption, the patentee must also show that the product is coextensive with the claimed features. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000); *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997). Even if Synthes had been able to show that its LCP products embody all the limitations of Claim 1, it failed to show that its LCP

[9] In explaining why the LCP products are not covered by Claim 1, the Board observed that the head of the LCP plates contains "holes for 'K-wire' and sutures that appear to be unthreaded." A64. The parties, however, have always treated the claims as requiring only threaded ***screw*** holes in the head of the plate. A11636 (Synthes Declarant: "the head portion of the plate contains only threaded bone screw holes"). The K-wire and suture holes are not screw holes. Nonetheless, the Board's finding that the LCP products are not covered by Claim 1 is supported by the reasons provided herein.

products are coextensive with Claim 1. For example, the Board found that the LCP plates contain Combi holes that are not disclosed in the specification or recited in any of the rejected claims. A63-64. Synthes does not challenge that finding on appeal. *See* Br. at 29. Indeed, Synthes' own expert admitted that the Combi holes are "threaded" and that they contributed to the commercial success of the LCP plates. A12890. Thus, due to the presence of Combi holes in all of Synthes' LCP plates, the LCP plates are not coextensive with Claim 1.

b. Synthes Failed To Establish A *Prima Facie* Case Of Nexus

Synthes argues that regardless of any presumption, it established a *prima facie* case of nexus through testimony of its employee and its expert and through evidence of market data. Br. at 25-26. But Synthes' evidence compares the sales of its LCP Products with its commercialized DCP plates. Those DCP plates were entirely non-locking, having only non-threaded holes throughout the plate. A11630; A12858-59. Synthes never compares its LCP plates' success against the closest prior art, the hybrid locking plates disclosed in the Koval article and K982222. But to prove a nexus, Synthes was required to show that the alleged success was "due to the merits of the claimed invention beyond what was readily available in the prior art." *J.T. Eaton*, 106 F.3d at 1571; *Ormco*, 463 F.3d at 1312 ("[I]f the feature that creates the commercial success was known in the prior art,

the success is not pertinent.").[10] Courts have long required this showing for commercial success to be probative of nonobviousness. *See Chicago Rawhide Mfg. Co. v. Crane Packing Co.*, 523 F.2d 452, 459 (7th Cir. 1975) ("If the critical reference came into existence, or was discovered, only a short time before the patented conception, commercial success may merely demonstrate nonobviousness as compared to the earlier, well known art, rather than when compared to the recent reference.").

Synthes' own evidence supports the Board's finding that its commercial success was due to the hybrid nature of its plates and not because the plate head has only threaded holes. For example, Mr. Haag explained that there was a clinical need for a new plating system because existing conventional bone plates did not use any locking screws or locking holes. A11630-32. According to Mr. Haag, Synthes recognized this clinical need and "conceived and developed a hybrid technology" — combining locking and non-locking holes — that allowed the LCP plates to gain widespread use. A11631. Mr. Haag further explained that "[l]ocking and hybrid plates and screws have been quickly adopted by the medical

[10] *See also Merck & Co. v. Teva Pharms., USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) ("Although commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the Lunar News articles.")

community, despite their significant price premium over standard plates and screws." A11637. Mr. Haag repeatedly compares Synthes' LCP plates to its DCP, non-locking plates, but never compares them to the Koval or K98222 hybrid prior-art plates. A11630-31; A11637-11640.

Synthes' Parsons declaration mirrors Mr. Haag's description of the development of the LCP products, characterizing the '486 patent as disclosing a "revolutionary bone plating system" that uses "both conventional and locking screws to combine the flexibility and compression benefits available with traditional LC-DCP products with the advantages of locking screws incorporated into one bone plating system." A11210. Dr. Parsons and Mr. Haag never asserted that the LCP plates were successful because their heads have only threaded holes.

The '486 patent cannot give Synthes exclusive rights to hybrid plating. Both Koval and K982222 unquestionably disclose a condylar buttress plate with both threaded and non-threaded holes. Recognizing this, the Examiner concluded that Synthes had not shown that the success was due to features not found in the prior art. A12810-11. In response, Synthes submitted a second declaration from its expert, Dr. Turen. However, Dr. Turen did not testify that the commercial success of the LCP plates was due to the plate having only threaded holes in the head. Rather, Dr. Turen testified that ***two*** features "contribute[d]" to the commercial success of the LCP plates: (1) having only threaded holes in the head and (2)

having threaded holes (*i.e.*, Combi holes) in the shaft. A12890. Thus, Synthes' own expert acknowledged that the unclaimed Combi holes contributed to the commercial success of the LCP plates. *Id.*

Given this admission and given that Synthes' own declarants testified that hybrid plates were a dramatic advance over conventional, non-locking bone plates, Synthes cannot show that the commercial success of the plates was due to having only threaded holes in the head.[11] *See Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) ("Asyst's failure to link that commercial success to the features of its invention that were not disclosed in [the prior art] undermines the probative force of the evidence pertaining to the success of [its] products."); *see also Pfaff v. Wells Elec., Inc.*, 124 F.3d 1429, 1439 (Fed. Cir. 1997), *aff'd*, 525 U.S. 55 (1998).

Thus, Synthes' own evidence demonstrates that the alleged success of the LCP plates did not stem from the plate having only threaded holes in the head, but instead stemmed from either the unclaimed Combi holes or the hybrid nature of the plate. Thus, the Board's finding of no nexus is supported by substantial evidence.

[11] The fact that the 4.5mm tibia plate includes non-threaded screw holes in the head and was nonetheless successful also suggests that the success of the LCP plates was not due to the only-threaded-holes-in-the head feature.

c. Smith & Nephew Rebutted Any Showing Of Nexus

The Board correctly found that Smith & Nephew rebutted any presumption or *prima facie* case of nexus with its evidence that there were many unclaimed features and market factors that contributed to the success of Synthes' LCP products. A63-64. That finding is supported by substantial evidence.

i. Unclaimed Features Contributed To The Commercial Success Of The LCP Products

The Board's finding that unclaimed features may have contributed to the commercial success of the LCP plates is supported by substantial evidence. "[I]f the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant." *Ormco*, 463 F.3d at 1312. Smith & Nephew's declarant, Mr. Donoghue, explained that many features of the LCP products not recited in Claim 1 contributed to the sale of the products. A12419-25. Indeed, the LCP bone plates are marketed and sold with various other components and instruments that contribute to the overall success of the LCP products. *Id.*

For example, all of the LCP plates have Combi holes in the shaft. *See supra* 33-34. As the Board correctly noted, these unique Combi holes are not disclosed or claimed in the '486 patent (A63-64), and are, in fact, separately patented by Synthes (A12551-52; A14572-81). A plate having Combi holes in the shaft offers advantages over a plate having non-threaded holes in the shaft. A11542; A11578; A11602. Indeed, Synthes prominently advertises the Combi holes as a unique

feature of its bone plates on the first page of its Technique Guides. *Id.*; A63-64. In contrast, its Technique Guides never mention that its LCP plates have only threaded screw holes in the head. *See*, *e.g.*, A11540-73. They merely identify the "six threaded screw holes" in the plate head in a list of twelve features on the following page. A11543; *see also* A11579 & A11603.

Smith & Nephew identified numerous other unclaimed features that contribute to the success of the claimed bone plates. For example, the LCP plates are sold as part of a kit that includes numerous other instruments and components, including an articulated tension device and corresponding hole, a large distractor, specialized drill bits, drill guides, screwdrivers, Kirschner wires and corresponding holes, torque limiting attachments, and others. A13938-43. Synthes prominently advertises these features. *See*, *e.g.*, A11543; A11565; A11579; A11588; A11603; A11607; A11612.

Synthes attacks the Board's finding as unsupported by substantial evidence. Br. at 32. Citing the Haag declaration, Synthes contends that it gained nearly 100% of the market share because "it was the only manufacturer to offer a plate with a fully-locking head portion." *Id.* (citing A11639). However, the Haag declaration does not support Synthes' assertion that the gain was due to the head having only threaded holes. Rather, as discussed above, the Haag declaration attributes the gain to "Synthes' hybrid technology." A11639. Again citing the

Haag declaration, Synthes argues that competitors succeeded in taking market share even though their products lacked Combi holes. Br. at 33. Thus, Synthes argues, the competitors' success must have been due to having only threaded holes in the head. *Id.* There is no evidence in the record, however, that these competitor plates contained only threaded screw holes in the head. In fact, the record is completely devoid of any evidence that competitor plates are even covered by Claim 1 of the '486 patent. Synthes' copying arguments, sprinkled throughout its brief without citation, are completely unsupported by the record. *See* Br. at 15-18, 32-35.

ii. Other Market/Commercial Factors Contributed To The Commercial Success Of The LCP Products

Smith & Nephew also provided testimony by Mr. Donoghue explaining that other market and commercial factors support the Board's finding of no nexus, including brand loyalty, use of group purchasing contracts, and Synthes' dominant market share. A12425-29.

Mr. Donoghue explained that a surgeon's training and familiarity with Synthes' bone plates and instruments gives rise to significant brand loyalty that contributes to the commercial success of all of Synthes' bone plating systems. A12425-27. He also explained how hospitals would be reluctant to switch from Synthes' bone plates to those of another company, because doing so could result in hospital inventory becoming useless. A12426.

Mr. Donoghue also explained how the important relationship between an orthopedic sales representative and the surgeon affects the sales of a company's bone-plating systems. A12426-27. He concluded that brand loyalty (resulting from the training on a given system, familiarity with a given system, and the sales representative relationship) is a significant and important factor affecting why the surgeon will choose to purchase and use a particular bone plating system. A12428.

Mr. Donoghue also explained that the trauma industry's use of GPO contracts contributes to the success and sales of Synthes bone plates. A12428-29. GPOs negotiate with orthopedic trauma manufacturers and hospitals under a comprehensive purchasing contract where the hospitals obtain preferential or discounted pricing if they agree to purchase all or a significant percentage of their trauma products using the GPO contract. *Id.* Mr. Donoghue further explained how Synthes' relationship with Novation, a large GPO, generated more than $2.5 billion in sales for Synthes. *Id.* He testified that the use of these type of contracts has significantly increased and that they "affect [the] market for bone plating systems and are an important factor influencing the purchasing decisions made by hospitals and doctors in terms of which bone plating systems are available for purchase and use." *Id.*

Mr. Donoghue also explained that Synthes possessed a dominant market share in the bone plating market that contributed to the commercial success of its

LCP products. A12429. Generally, sales figures from a market leader are not afforded great weight in the commercial success analysis. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 316 (Fed. Cir. 1985); *Schwinn Bicycle Co. v. Goodyear Tire & Rubber Co.*, 444 F.2d 295, 300 (9th Cir. 1970).

Mr. Donoghue testified that in 2003— just two years after Synthes launched its LCP products — Synthes sold 70.6% of the medium bone plates and 59.5% of the large bone plates in the United States (measured by units). A12429. He further testified that "[t]his market power provides Synthes with significant advantages and is another important economic or commercial factor affecting how bone plating systems are purchased in the United States." *Id.*

Mr. Donoghue also cited a 2005 report on the orthopedics market that described how various market factors contribute to Synthes' successful sales of its products:

> Having compared all new plating systems with Synthes' existing offering, due to Synthes' brand name, its technology advantage, its product quality, the broadness of its offering and its AO-ASIF based unique relationship with the scientific world, we do not believe that any competitor will capture a single account from Synthes -- provided they do not operate with extensive price cuts or kick-backs.

A12429 (quoting A12454).

Synthes attacks Smith & Nephew's market-power and GPO-contract evidence as not being the "primary causes" of the LCP products' success. Br. at 34. Synthes cites Mr. Haag's declaration to support its view that the plates

"technical advantage" was the cause. *Id.* While Synthes does not identify a specific technical advantage associated with the LCP plates, the Haag declaration repeatedly stresses the hybrid nature of the LCP plates over the DCP and LC-DCP plates and never mentions the feature of having only threaded holes in the head. A11630-31. In sum, Smith & Nephew's evidence of other market and commercial factors is substantial evidence that supports the Board's finding of no nexus.

d. The Board Did Not Require Synthes To Show That The Alleged Success Was Due To Claimed Features "Alone"

Synthes mischaracterizes the Board's decision as requiring Synthes to establish that the claimed invention was the *exclusive* cause of the alleged commercial success. Br. at 27. The Board imposed no such requirement.

In order to establish nexus, Synthes had to show that its commercial success was "a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter." *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996). Once Smith & Nephew presented its rebuttal evidence regarding unclaimed features and other market factors, Synthes was obligated to rebut this evidence. However, as the Board found, Synthes utterly failed to "proffer rebuttal evidence, arguments or explanation to address the possible impact of 'Combi holes'" and did not "adequately address[] other factors that may have had significant bearing on the

commercial success of the kits, and in particular, group purchasing contracts." A64.

Synthes attacks the Board's finding that unclaimed features and other market factors contributed to the commercial success of the LCP plates, because the Board used the phrase "may have" instead of more definitive language. Br. at 29. Synthes had the burden, however, to show that the commercial success of its LCP products was "directly attributable" to the features of Claim 1. *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012). Smith & Nephew needed only to point to unclaimed features or market forces that "***could*** have contributed to the commercial success" of Synthes' LCP products. *Id.* at 1363-64 (emphasis added); *see also Pentec*, 776 F.2d at 316 (patent owner failed to show nexus where commercial success "may" have been due in large part to other economic and commercial factors).

The cases cited by Synthes merely stand for the proposition that once the parties have submitted their evidence, the district court is to give the evidence the appropriate weight under the totality of the circumstances. *See Cont'l Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1273 (Fed. Cir. 1991) (vacating district court's grant of summary judgment of invalidity due to obviousness and holding that it is not necessary that the patented invention be solely responsible for the commercial success "in order for this factor to be given weight appropriate to the

evidence, along with other pertinent factors."); *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1393 (Fed. Cir. 1988) ("Once a prima facie case of nexus is made the court must consider the evidence adduced on both sides of the question, with such weight as is warranted.").

Here, the Board considered Synthes' evidence of commercial success, but rightfully gave it little weight in light of Synthes' own declarants' admission that features found in the prior art (such as hybrid plating) and unclaimed features (such as the Combi holes) contributed to the commercial success of the LCP plates. Accordingly, substantial evidence supports the Board's finding of no nexus between the commercial success of Synthes' LCP products and Claim 1.[12]

3. Synthes' Proffered Evidence Of Commercial Success Cannot Overcome The Strong Obviousness Case

In the '744 decision, this Court acknowledged the closeness of the prior art to substantially similar claims and concluded that there was "compelling evidence that it would have been obvious to modify any one of the three primary references to have only threaded holes in the head portion." *Smith & Nephew*, 721 F.3d at 1380. Indeed, given the similarly compelling *prima facie* case of obviousness in this case, Synthes' proffered evidence of commercial success cannot overcome the

[12] Synthes' legal arguments and assignment of error on the issue of presumption, *see* Br. at 22-25, are academic in light of the rebuttal evidence offered by Smith & Nephew and the Board's consideration of all of the evidence submitted.

strong obviousness case. *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Asyst*, 544 F.3d at 1316; *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1344 (Fed. Cir. 2008).

Synthes argues that "when viewed through the lens of Synthes' evidence of commercial success, the prior art does not render the '486 patent obvious." Br. at 35-42. Synthes then proceeds to reargue the merits of the prior art, raising arguments already rejected by this Court in the Prior Appeal. For example, Synthes reargues that Koval and K982222 maintained two non-threaded holes in the head, because "one of ordinary skill in the art at the time believed that the ability to use non-locking, compression screws in the head was necessary." Br. at 38. This Court rejected that argument, noting that "claim 1 of the '744 patent did not require that the head screws provide compression," and, nonetheless, the '744 patent admitted that non-locking screws could be used in threaded holes to provide compression. *Smith & Nephew*, 721 F.3d at 1377-78. Here, Claim 1 of the '486 patent also does not require compression, and the '486 patent contains the same admission as the '744 patent. A7395.

Synthes also argues that "one of ordinary skill in the art would not have been motivated to modify the primary references to include threaded holes of the type disclosed in Haas [*i.e.*, conically shaped holes]," for various reasons, including that the screw would sit high and protrude above the plate. Br. at 39-40. This Court

rejected those arguments, holding that it would have been trivial to use a chamfer to sink the screw head or to use a conically shaped screw, which could sit in the Haas hole without protruding. *Smith & Nephew*, 721 F.3d at 1378.

Moreover, Synthes cites to its own experts' declarations in support of its repeat arguments, ignoring that Smith & Nephew submitted contrary evidence throughout the '486 reexamination. A12073-128; A12419-30; A12965-75. Synthes also ignores that Claim 1 does not require conically shaped holes. Finally, Synthes never explains how its alleged evidence of commercial success warrants a different outcome in light of the strong *prima facie* case of obviousness. Accordingly, this Court should affirm the Board's rejection of Claim 1 of the '486 patent as unpatentable for obviousness.

VI. CONCLUSION

Synthes has shown no reason why collateral estoppel does not apply to preclude Synthes from relitigating the patentability of a bone plate having only threaded holes in the head. Even if Synthes could overcome the collateral estoppel effect of this Court's opinion in the Prior Appeal, Synthes has shown no error warranting reversal of the Board's holding that Claim 1 of the '486 patent is unpatentable for obviousness. Accordingly, this Court should affirm.

Respectfully Submitted

Dated: July 18, 2014 By: */s/Joseph R. Re*

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ADDENDUM

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 32 Page: 61 Filed: 07/18/2014 Page: 61 Filed: 07/18/2014

The statute provides that a fee may be charged for "services provided" after the date on which the Board "first makes a final decision in the case." It is undisputed that the work performed by Mr. Cameron, for which he is claiming attorney fees, took place after the Board's March 16, 2005 final decision. In my view, for that reason, Mr. Cameron's claim is covered by the language of § 5904(c)(1).

The majority, though, concludes that the work performed by Mr. Cameron after March 16, 2005, and prior to July 19, 2005, which consisted of drafting letters to the RO, did not rise to the level of "services" within the meaning of the statute. In reaching that conclusion, the majority notes that, at most, all Mr. Cameron did following the Board's remand was send two letters to the RO requesting a decision. *See* Majority Op. 1369–70. According to the majority, that work did not constitute the providing of legal services: "[W]hen an RO simply implements the relief granted in the first final Board decision, there are no services to be provided by an attorney to the veteran." *See id.* at 8.

As a matter of policy, the majority's decision has much to recommend it. It can quite reasonably be argued that Mr. Cameron should not be able to recover attorney fees for the extremely limited work he performed. The problem I have with the majority's approach is that I am unable to find anything in the statutory language which limits the meaning of the word "services" in the way the majority does. If Congress had wished to limit the circumstances under which work performed by an attorney after a final Board decision qualifies as "services provided," it could easily have done so.

In my view, however, the statute does provide a way of addressing the circumstances presented by a case such as this. Pursuant to the prior version of 38 U.S.C. § 5904(c)(2) relevant to this appeal, "[t]he Board, upon its own motion or the request of either party, may review such a fee agreement and may order a reduction in the fee called for in the agreement if the Board finds that the fee is excessive or unreasonable." I see nothing to prevent the Board from considering, on its own motion, whether the fee claimed by Mr. Cameron in this case is unreasonable and then reducing the fee if it determines that it is unreasonable.

For the reasons set forth above, I would hold that the Board and the Court of Appeals for Veterans Claims ("Veterans Court") erred in holding that the work performed by Mr. Cameron that is at issue did not qualify as "services" under prior § 5904(c)(1). I therefore would reverse the Veterans Court's decision and would remand the case with the instruction that the court, in turn, remand the case to the Board for the Board to determine the amount of fee to which Mr. Cameron is entitled, noting that the Board has the authority under prior § 5904(c)(2) to consider, on its own motion, the reasonableness of the fee claimed by Mr. Cameron.

SMITH & NEPHEW, INC., Appellant,

v.

Teresa Stanek REA, Acting Director, United States Patent and Trademark Office, Appellee,

and

Synthes (U.S.A.), Appellee.

No. 2012–1343.

United States Court of Appeals, Federal Circuit.

July 9, 2013.

Background: Board of Patent Appeals and Interferences reversed decision of pat-

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 33 Page: 62 Filed: 07/18/2014 Page: 62 Filed: 07/18/2014

ent examiner and held that certain claims of patent directed toward system for using plates to repair bone fractures in long bones, such as the femur, would not have been obvious and therefore were not invalid, 2012 WL 169750. Entity that requested reexamination appealed.

Holding: The Court of Appeals, Bryson, Circuit Judge, held that patent was invalid on obviousness grounds.

Reversed.

1. Patents ⇐16.14

Use of only conical, partially threaded holes in head portion of bone plating system so that surgeon could choose to use locking or non-locking screws to impart compression between head portion and bone would have been obvious, and thus patent directed toward such system was invalid, since holes in prior art plate were both partially threaded and fully conical, prior art disclosed use of non-locking screws in threaded holes to achieve compression, and having only threaded holes in head portion of bone plating system would have been obvious.

2. Patents ⇐113(1)

Court of Appeals could review determination that Board of Patent Appeals and Interferences had considered and rejected even if argument had not been presented in appeal briefs to Board.

3. Patents ⇐16.14

Claim in patent regarding use of only conical, partially threaded holes in head portion of bone plating system so that surgeon could choose to use locking or non-locking screws to impart compression between head portion and bone could not be distinguished from prior art to avoid invalidity on basis of obviousness on ground that threads in holes of prior art did not entirely surround locking screw, since difference between thread that surrounded screw and one that only partially surrounded screw was one of degree only.

4. Patents ⇐113(6)

Substantial evidence standard of review that required deferential approach to findings of Board of Patent Appeals and Interferences on reexamination did not preclude Court of Appeals from reversing decision of Board as to whether patent was obvious, where facts were largely undisputed and Board's decision was mainly result of analytical errors.

5. Patents ⇐113(6)

Expert opinions that are contrary to admissions in the specification do not create a factual issue under the substantial evidence standard of review of a decision by the Board of Patent Appeals and Interferences on reexamination regarding obviousness.

Patents ⇐328(2)

5,709,686. Cited as Prior Art.

Patents ⇐328(2)

7,128,744. Invalid.

Joseph R. Re, Knobbe, Martens, Olson, & Bear, LLP, of Irvine, California, argued for appellant. With him on the brief was Christy G. Lea. Of counsel on the brief were Robert A. King and David A. Kelly, Hunton & Williams, LLP, of Atlanta, Georgia; and Bradley T. Lennie, Rodger L. Tate, and Jeffrey B. Vockrodt, of Washington, DC.

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 33 Page: 63 Page: 63 Filed: 07/18/2014 Filed: 07/18/2014

Kristi L.R. Sawert, Associate Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia, argued for appellee, United States Patent and Trademark Office. With her on the brief was Brian T. Racilla, Associate Solicitor. Of counsel was Nathan K. Kelley, Deputy Solicitor.

David R. Bailey, Woodcock Washburn LLP, of Philadelphia, Pennsylvania, argued for appellee, Synthes (U.S.A.). With him on the brief were William F. Smith and John F. Murphy.

Before DYK, BRYSON, and WALLACH, Circuit Judges.

BRYSON, Circuit Judge.

Appellant Smith & Nephew, Inc., seeks review of a decision of the Board of Patent Appeals and Interferences (now known as the Patent Trial and Appeal Board). Reversing the decision of a patent examiner, the Board held that certain claims of a patent owned by appellee Synthes (U.S.A.) would not have been obvious and therefore were not invalid. Both Synthes and the Acting Director of the Patent and Trademark Office have filed briefs supporting the Board's decision. While the "substantial evidence" standard of review for the Board's factual findings makes Smith & Nephew's burden on appeal a heavy one, we are satisfied, after careful review, that Smith & Nephew has met that burden and has shown that the claims at issue would have been obvious. We therefore reverse the decision of the Board.

I

Synthes owns U.S. Patent No. 7,128,744 ("the '744 patent"). The patent was issued in 2006, and it claims priority to a provisional application filed on September 13, 1999. The patent is directed to a system for using plates to repair bone fractures in long bones, such as the femur. The bone plate that is the subject of the patent runs along the outside of the fractured bone and is attached by bone anchors (typically, bone screws) that are inserted through predrilled holes in the plate and then into the bone. The dispute in this case focuses on the structure of the holes in the plate through which the screws are inserted.

In 2009, Smith & Nephew requested reexamination of the '744 patent, and the Patent and Trademark Office granted the request. After reviewing detailed evidentiary submissions, the examiner rejected all 55 claims of the '744 patent as obvious based on a number of prior art references. Synthes appealed the rejections to the Board of Patent Appeals and Interferences, which upheld the rejections of 31 of the claims (claims 24–31 and 33–55), but reversed the rejections of 24 of the claims (claims 1–23 and 32). Smith & Nephew appeals from the Board's decision with respect to the 24 claims on which the Board reversed the rejections.

A

The parties have treated claim 1 as representative of the 24 claims of the '744 patent that survived the reexamination, and we do the same. Claim 1 recites a bone plating system for improving the stability of a bone fracture in a long bone, comprising a bone plate having a shaft portion that is configured to run along a portion of the bone and a head portion that flares out from the shaft portion so as to accommodate the wider portion of the bone near a joint. The head portion has at least three bone anchor holes, all of which are conically tapered from the top surface

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 32 Page: 64 Filed: 07/18/2014 Page: 64 Filed: 07/18/2014

of the plate to the bottom surface.[1] All of the holes in the head portion are at least partially threaded to engage the threads on the head of a "locking" bone anchor (or screw). The shaft portion of the claimed plate has a plurality of holes in which at least a portion of the hole is threaded. The central issue in this case is whether it would have been obvious at the time of the invention to design a bone plate in which all of the holes in the plate's head portion were conically tapered and at least partially threaded to engage threaded "locking" screws.

The '744 patent describes two basic types of screws that were used in prior art bone plates. First are nonlocking compression screws, which have threaded shafts but unthreaded heads and which typically pass through unthreaded holes in the plate. Upon being tightened, the compression screws draw the bone and plate together. Second are locking screws, which have threaded heads as well as threaded shafts. The threads on the heads of the locking screws engage with corresponding threads on the interior of the anchor holes in the plate, which results in fixing the screws to the plate.

The two types of screws perform different functions: compression (non-locking) screws draw the bone and the plate together for fracture reduction and quicker healing, while locking screws fix the relative position of the plate and bone so that the plate does not move relative to the bone. See '744 patent, col. 1, line 64–col. 2, line 7. The latter feature is especially important when the bone is a weight-bearing bone that is subject to pressure that can loosen the connection between the screws and the plate if only conventional compression screws are used to attach the plate to the bone.

Several commercial bone plates, as well as articles and descriptions of bone plates, are acknowledged to be prior art to the '744 patent. First is a condylar buttress plate that Synthes marketed in the 1990s. Designed for fractures in the femur near the knee, the Synthes plate had a shaft and head portion, both of which contained unthreaded holes designed for compression screws.

A 1997 article by Kenneth Koval described a modified version of the Synthes condylar buttress plate. In the Koval plate, threaded nuts were welded onto the top of four of the six holes in the head portion of the plate, enabling the use of locking screws in those holes.

In a 1998 prior art submission to the Food and Drug Administration, referred to as the K982222 application, Synthes sought permission to market a plate having four threaded holes and two unthreaded holes in the head portion of the plate. That device, like the Koval plate, allowed locking screws to be used in the head portion. The Koval plate and the K982222 application followed the suggestion in a 1996 article by Brett R. Bolhofner (one of the inventors of the '744 patent) and others, which noted a means of solving the problem that screws "can angulate . . . and are not fixed in a constant relationship" to the plate by "selective locking of the screws to the plate."

In 1997, N.P. Haas published an article describing a version of the Synthes plate

1. Smith & Nephew argues that the Board erred in construing the claim to require that all of the holes in the head be conically tapered. It is unnecessary to decide that issue to resolve the invalidity contention, so for present purposes we accept the Board's construction of the claim.

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 32 Page: 65 Filed: 07/18/2014 Page: 65 Filed: 07/18/2014

that used only conically tapered, threaded holes in the shaft and head portions of the plate. Unlike other prior art plates, this one merely stabilized the femur and did not compress or even contact bone fragments directly.

The prior art background also included plates for fractures not involving the femur. During the 1990s Synthes marketed a Distal Radius Plate ("DRP") for wrist fractures. The anchor holes of the DRP were all partially threaded and, importantly, were specifically designed for use with either locking screws or non-locking, compression screws. In 1997 Synthes marketed another device, known as the Locking Reconstruction Plate ("LRP"), which was designed to serve as an internal fixation plate for a lower jaw fracture. That plate, and a patent application for a similar device that ultimately issued as U.S. Patent No. 5,709,686 ("the '686 patent"), featured anchor holes that were all partially threaded and were intended to accommodate either locking screws or compression screws.[2] The screw holes in the LRP had a threaded lower portion and an unthreaded, conically flared upper portion that enabled the screws to be countersunk so that the heads of the screws did not extend above the surface of the plate.

At the conclusion of the reexamination, the examiner rejected all of the claims of the '744 patent. He rejected the claims at issue in this appeal based on three separate combinations of prior art references: the K982222 application and the Haas article; the Koval and Haas articles; and the Synthes device and the Haas article. In the examiner's view, combining any of the bone plates in the prior art with the conically tapered, threaded holes used in the Haas reference taught all the limitations of the claims in dispute. As for the motivation to combine features in the prior art, the examiner adopted Smith & Nephew's argument that the claimed configuration was an attractive option because using locking screws would maximize the stability of the head of the plate, and using threaded screw holes would give the surgeon the option during surgery to use either locking screws or compression screws in the threaded holes, depending on whether compression or stabilization was preferred at the particular position of each of the plate holes.

B

On appeal, the Board reversed the rejections as to claims 1–23 and 32. The Board concluded that it would not have been obvious to modify the condylar buttress plate in the prior art by having only threaded holes in the head portions of that plate. The Board acknowledged that persons of skill in the art would have been motivated to include threaded holes for locking screws in the head portion.[3] However, the Board concluded that the prior art references suggested only that some of the holes in the head portion should be partially or wholly threaded, not that *all* of them should be partially or wholly threaded. The Board further concluded that the evidence of record was insufficient to show that inserting conventional screws in the tapered, threaded holes recited in claim 1 could impart compression between the

2. The '686 patent does not specify what fractures the invention was intended to mend.

3. Both parties' experts agreed that a person of skill in the art would include an orthopedic surgeon with two years' experience in the design or implantation of bone plates or similar orthopedic implants.

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 33 Page: 66 Filed: 07/18/2014 Page: 66 Filed: 07/18/2014

head portion of the buttress plates and the bone, and for that reason the Board held that the examiner's obviousness analysis was not "based on adequate rational underpinnings."

The Board acknowledged that the specification of the '744 patent referred to the '686 patent, which disclosed a bone plate in which all of the holes were partially threaded, and that the specification stated that the partially threaded holes of the '686 patent "allow either non-locking or locking screws to be used." '744 patent, col. 2, ll. 17–18. However, the Board distinguished the holes described in claim 1 of the '744 patent from the holes of the '686 patent on the ground that the former were "conically tapered from the upper surface to the lower surface" of the plate, while the holes of the '686 patent "include an unthreaded conically flaring area . . . and a separate threaded straight portion." A hole that is conically tapered from the upper surface to the lower surface, the Board stated, is disclosed in the record only by the threaded holes of the Haas prior art reference. Because the holes disclosed in Haas were not shown to accept non-locking screws that would allow for compression, the Board concluded that the evidence did not establish that partially threaded plate holes that are conically tapered from the upper surface to the lower surface were known to be suitable for use with both locking and non-locking screws.

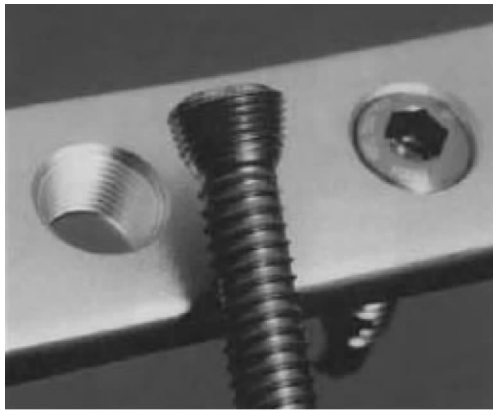
The Board rejected the argument that a person of ordinary skill in the art would have used conventional bone screws in the conical tapered holes of Haas, partly on the ground that the heads of the screws would "sit[ ] high atop the plate," thereby causing patient discomfort and other possible complications. The Board relied on the declaration of one of Synthes's experts, Clifford H. Turen, who stated that a conventional condylar plate screw had a "rounded-bottom head" that would stick out from a conical hole. The Board noted that the Haas plates used chamfers to countersink its screws into conical holes, but it found that the chamfering shown in Haas "is very small and shallow," and therefore could not be used to countersink conventional condylar buttress plate screws.

II

The Synthes prior art condylar buttress plate discloses most of the limitations of claim 1 of the '744 patent. It consists of a bone plate with a shaft portion having arched cut-outs on its lower surface. The head portion contains at least three screw holes. The modifications of that plate represented by the Koval and K982222 prior art references contain four holes in the head portion that are partially threaded to engage the threads on the head of a locking screw. The Haas secondary reference includes holes in the head portion that are both conically tapered and partially threaded. The photographs below show the prior-art Synthes condylar buttress plate and the conical, partially threaded holes of Haas:

Synthes Plate

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 32 Page: 67 Filed: 07/18/2014 Page: 67 Filed: 07/18/2014



Haas's conical, partially threaded holes

The essence of the analysis that led the Board to overturn the examiner's decision can be summarized as follows: The prior art references did not teach or suggest the exclusive use of conical, partially threaded holes in a condylar buttress plate because it was not believed that those holes could be used with non-locking screws to provide compression. While the '744 specification stated that the partially threaded holes of the '686 patent could be used with non-locking screws to obtain compression, the Board did not treat that admission as fatal to Synthes's case because the holes in the plates of the '686 patent were not fully conical from the top surface to the bottom surface of the plate, as required by claim 1. And although the holes in the Haas plate were both threaded and fully conical, the Board determined that one of ordinary skill would not have used a standard screw in the kind of hole disclosed in Haas because there was no evidence that conical, partially threaded holes were known to be suitable for use with both non-locking and locking screws, and because using a conventional bone screw in a conical tapered hole with a small chamfer, as in Haas, would result in the screw head sitting unacceptably high above the bone plate.

A

There are several problems with the Board's analysis.

[1] First, to the extent that the Board based its ruling on its conclusion that it would not have been obvious to use a standard compression screw in a threaded hole to obtain compression, the Board overlooked the fact that claim 1 of the '744 patent did not require that the head screws provide compression. If a physician regarded it as preferable to have stabilization rather than compression in the head portion of a bone plate, an obvious solution would have been to use more threaded holes and locking screws in that part of the plate. Contrary to Synthes's suggestion that compression is invariably needed in the head portion of condylar buttress plates, the '744 specification indicates that locking screws are sometimes used in all of the threaded holes of the head portion of the bone plate. '744 patent, col. 6, ll. 47–50 ("generally, threaded holes 56b, 56c [the screw holes in the head portion] are arranged so that the inserted locking screws converge toward each other"). As an alternative to using all locking screws in the head holes, the specification provides that non-locking screws can be substituted for locking screws in any of

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 33 Page: 68 Filed: 07/18/2014 Page: 68 Filed: 07/18/2014

those holes "if a surgeon elects." *Id.* Accordingly, the embodiment in which locking screws are used in all of the head screw holes would not provide compression in the head portion of the plate, but would still be within the scope of claim 1.

[2] Second, the Board's conclusion that using a standard compression screw in a conical, partially threaded hole would cause the screw to protrude above the line of the plate is the result of not reading the prior art for all that it teaches. The plate hole illustrated in Haas contains a chamfer, and it is undisputed that a chamfer can be used to countersink a screw head so that it does not sit above the top surface of the plate.[4] The Board's observation that the chamfer in Haas is narrow ignores the point that the disclosure of a chamfer is not limited to the precise size of the chamfer depicted in the illustration of the Haas device. Chamfers are conventional features in the art and can be sized to accommodate screw heads of varying heights. Nothing about the Haas reference limits the size of the chamfer or in any way suggests that it could not be made larger than it appears to be in the drawings contained in the Haas reference. In any event, even the illustrations in the Haas reference make clear that the chamfer in Haas is large enough to allow the screw to be countersunk so that it does not protrude above the level of the plate. That portion of the Board's analysis therefore does not provide a basis for disregarding the chamfer disclosed in Haas.[5]

Even if countersinking were not an option, a person of ordinary skill would not have had to use a screw with a "rounded-bottom head" that would stick out from the plate. Instead, a conically shaped screw could sit in the Haas holes without any risk of protrusion. The '744 specification states, as a general proposition, that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry for select plate holes of the bone plate can be used" in the claimed bone plate. '744 patent, col. 4, ll. 20–22. The patent thus suggests the choice of any appropriate screw design rather than limiting the choice to a screw that would sit too high in a conical hole.

Third, the Board's reliance on the fact that the partially threaded holes in the '686 patent are only partly conical (and partly cylindrical) does not undermine the '744 patent's admission that partially threaded holes, regardless of their shape, could provide compression. Neither the Board nor Synthes has argued that there is anything about the Haas fully conical shape that would suggest that a standard, non-locking screw could not have been used in such a hole to achieve compression. As already noted, the '744 specification indicates that "any surgical screw that has a non-threaded head . . . of an appropriate size and geometry" can be used to practice the invention. '744 patent, col. 4, ll. 20–22. The patent confirms what common sense suggests: a person of skill could adjust a plate hole's geometry—whether conical, cylindrical, or otherwise—

4. Synthes argues that Smith & Nephew waived this argument by not presenting it in its appeal briefs to the Board. However, because the Board considered and rejected the argument as properly raised, we may review that determination.

5. Figures 9 and 22 of the '744 patent demonstrate that, even in the claimed invention, the screw may protrude above the surface of the plate. Synthes does not indicate what constitutes an "unacceptably high" screw position, or why countersinking could not have been used to limit or avoid the protrusion problem.

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 33 Page: 69 Page: 69 Filed: 07/18/2014 Filed: 07/18/2014

to fit any standard screw without sacrificing compression. In fact, in the portion of its opinion upholding some of the examiner's rejections, the Board specifically found that although the prior art plates—Synthes, Koval, K982222, and Haas—all used a "different type of threaded holes for receiving corresponding locking screws, use of any of those threaded holes [including the fully conical holes of Haas] would have been obvious to one of ordinary skill."

The discussion of the '686 patent in the '744 specification does not focus on the fact that the holes of the '686 patent are only partially conical. Instead, the discussion indicates that because the holes of the '686 patent are partially threaded, either locking or non-locking screws can be used. Curiously, the '744 specification goes on to state that "[b]ecause the plate holes are only partially threaded, the locking screws used may not be able to maintain the fixed angular relationship between the screws and plate under physiological loads." '744 patent, col. 2, ll. 18–21. Yet the disputed claims of the '744 patent recite that the holes in the head portion of the plate have "at least a portion that has a thread to engage a thread on a head of a bone anchor." Thus, the '686 patent cannot be distinguished on the ground that its holes are only partially threaded, since the claims of the '744 patent themselves recite holes that may be only partially threaded.

[3] To the extent that the '744 specification distinguished the '686 patent on the ground that the threads in the holes of the '686 patent do not entirely surround the locking screw (a point made by one of Synthes's experts), the difference between a thread that surrounds the screw and one that only partially surrounds the screw is one of degree only and is not a distinction on which validity turns. Not surprisingly, the Board did not rely on that distinction in its decision.

The '744 specification's description of the '686 patent therefore discloses that the prior art used non-locking screws in threaded holes. Because that prior art reference demonstrated that non-locking screws could achieve compression in either type of hole, the motivation to combine the Haas holes with the condylar plates was clear: The use of threads in all of the holes would offer the advantage of added flexibility for the surgeon, who could choose to use locking or non-locking screws in any of the holes in the head portion of the plate.

Fourth, the Board refused to consider two prior art references, the DRP and the LRP, which, like the '686 patent, disclosed the use of non-locking screws in threaded holes. The Board discounted those references on the ground that the examiner had not relied on them as a basis for his rejections. The examiner, however, incorporated Smith & Nephew's arguments by reference, including its discussion of those two references. The references were clearly probative as to whether it was known at the time of the invention that non-locking screws could be used in threaded holes. As such, they supported Smith & Nephew's rebuttal of Synthes's argument that the combination of the prior art condylar buttress plates with Haas would have rendered the prior art plates inoperable, on the theory that compression could not be obtained without at least some unthreaded holes in the head portion of the plate.

Synthes marketed the LRP and the DRP in the 1990s. The LRP was intended to deal with mandible fractures. In its brief to the Board, Synthes admitted that the plate holes in the LRP were designed so that the holes could "either be used to

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 37 Page: 70 Filed: 07/18/2014 Page: 70 Filed: 07/18/2014

form a locking construct or a nonlocking construct." That was because the holes had a lower threaded portion for providing a locking function with locking screws and an unthreaded upper portion "for providing a seating surface for use with the unthreaded head of a standard [compression] screw."

The DRP was intended to deal with wrist fractures. That plate featured holes in the "distal arm" portion of the plate that were all partially threaded and were specifically designed for use with either locking screws or nonlocking, compression screws. Although Synthes notes that neither the LRP nor the DRP are used with weight-bearing bones and therefore use holes with only "minimal threading," that does not meaningfully distinguish them from the claimed invention, which also requires only partially threaded holes.

[4] Finally, as already noted, the '686 patent disclosed the use of partially threaded holes to accommodate either locking or non-locking screws. Synthes acknowledged as much in the specification of the '744 patent. That intrinsic evidence from the '744 specification was plainly relevant and admissible to rebut Synthes's argument that such a structure would not have been obvious because it would not have worked.

[5] We recognize, of course, that the "substantial evidence" standard of review requires a deferential approach to the Board's findings. *In re Gartside*, 203 F.3d 1305, 1316 (Fed.Cir.2000). In this case, however, the facts are largely undisputed, and the Board's decision regarding the obviousness of including only threaded holes in the head portion of the condylar plate was mainly the result of the analytical errors discussed above, not the Board's resolution of factual questions.[6] Accordingly, we conclude that the Board erred in ruling that removing the nonthreaded holes from the head portion of the prior art plates would not have been expected to allow the plates to impart compression between the head portion and the bone.

B

Given the compelling evidence that it would have been obvious to modify any one of the three primary references to have only threaded holes in the head portion, the sole remaining feature that distinguishes the plate system of claim 1 from the prior art condylar plate systems using partially threaded holes is the fully conical shape of the holes in the plate recited in claim 1. And that feature is found in the secondary reference, Haas. Accordingly, the critical remaining question is: Would it have been obvious to a person of ordinary skill in the art to combine the partially threaded holes of the Synthes device, the Koval article, or the K982222 submission with the partially threaded, conical holes of Haas?

The evidence before the Board does not indicate that the choice of a fully conical

6. To the extent that Synthes sought to create a factual dispute through the declaration of Dr. Turen that "one of ordinary skill in the art would not have thought it to have been obvious to replace all of the unthreaded holes in the head portion of the plates disclosed in the primary references," that statement is contrary to the statement in the patent that the prior art taught partially threaded holes that "allow either non-locking or locking screws to be used," '744 patent, col. 3, ll. 17–18, as well as the LRP and DRP references. Expert opinions that are contrary to admissions in the specification do not create a factual issue. *See PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361–62 (Fed.Cir.2007).

Case: 14-1136 Case: 14-1136 CASE PARTICIPANTS ONLY Document: 33 Document: 37 Page: 71 Filed: 07/18/2014 Page: 71 Filed: 07/18/2014

hole, as opposed to a partially conical hole, would produce a surprising result or involve anything more than a choice among designs already found in the prior art. Synthes has not suggested that using a fully conical hole, as opposed to a hole that is partially conical and partially cylindrical, confers some significant advantage, nor is there anything in the '744 specification to suggest any such advantage.[7] Moreover, the prior art made clear that after substituting conical, partially threaded holes for the unthreaded holes in the head portion, the device still "would have worked for its intended purpose," even assuming Synthes's contention that achieving compression was the primary intended function of the claimed plate. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed.Cir.2009). This case is therefore one that falls within the Supreme Court's characterization of obviousness as entailing an improvement that is no "more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007).

Both in its brief and at oral argument, Synthes argued that achieving compression with non-locking screws in conically tapered, partially threaded holes was unknown in the prior art and, in fact, would have been inoperable. This naturally raises the question of how Synthes managed to make such a combination work. Obtaining compression in threaded holes, according to Synthes, became possible only through the use of a "specialized" or "specially-designed" screw devised for that purpose. But the patent does not claim or otherwise disclose any such "specially designed" screw. Upon being pressed at oral argument to identify the "specially designed screw" to which Synthes alluded in its brief, counsel for Synthes pointed to Figure 1 of the patent. That figure, however, is not identified in the patent as a "specialized" or "specially designed" screw. To the contrary, the specification refers to Figure 1 as merely "an example of a non-locking screw" and states that "any surgical screw that has a non-threaded head ... of an appropriate size and geometry for select plate holes of the bone plate can be used." '744 patent, col. 4, ll. 18–22.

The problem with Synthes's argument is that it is contending that a standard non-locking screw would be inoperative to obtain compression in a threaded hole, while at the same time claiming that it managed to achieve exactly that objective, all through the *deus ex machina* of a "specialized screw." But an unclaimed and undisclosed feature such as the "specialized screw" cannot be the basis for finding Synthes's patent to be non-obvious over the prior art. *See E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed.Cir.1988), quoting *McCarty v. Lehigh Valley R. Co.*, 160 U.S. 110, 116, 16 S.Ct. 240, 40 L.Ed. 358 (1895) ("[N]o principle of law ... would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty....").[8]

The patentability of the invention at issue in this case turns on the structure of the holes, not the special nature of the non-locking screw that is to be used with those holes. The conical, partially thread-

7. Synthes has not relied on any objective indicia of non-obviousness, such as commercial success, to buttress its case.

8. Counsel for the Acting Director specifically disclaimed reliance on any "specialized screw" supposedly disclosed in the patent.

Case: 14-1136 Case: 14-1136 PARTICIPANTS ONLY Document: 33 Page: 72 Filed: 07/18/2014 Case: 14-1136 Page: 72 Filed: 07/18/2014

ed holes themselves were well known in the art, as was the advantage of adding more of them to the head of a condylar bone plate in place of unthreaded holes. Both the screws and the holes perform their conventional, expected function in securing the plate. Because we hold that the examiner correctly ruled that disputed claims would have been obvious, we reverse the decision of the Board.

REVERSED

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Filed: IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system on July 18, 2014.

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CERTIFICATE OF COMPLIANCE UNDER FED. R. APP. P. 32

Appellee Smith & Nephew, Inc. (hereinafter "S&N") submits its brief under Rules 32(a)(5)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

As required by Rule 32(a)(7)(C), I hereby certify that S&N's brief complies with the type-volume limitation therein provided, and that S&N's brief contains approximately 10,523 words, including headings, footnotes and quotations. I further certify that S&N's brief complies with the typeface and type style requirements of the Federal Rules of Appellate Procedure 32(a)(5)(A) and 32(a)(6) by using 14-point proportional spacing in a Times New Roman font. The word processing program used for this brief is Microsoft Word, 2003.

Respectfully submitted,

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